

this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

*Amendments*

*In the Claims:*

Please cancel claims ~~2, 8, 23-29, 36, 37, 51-65, 68, 75, 76, 82, 87, and 88-103~~ without prejudice or disclaimer.

Please substitute the following claim 1 for the pending claim 1:

*Sub B1* 1. (Once amended) A method of treating cancer or metastasis thereof in a mammal, comprising:  
*Act*  
administering into a muscle of said mammal a non-infectious, non-integrating DNA encoding a cytokine or an active fragment thereof, through operable association with one or more transcription control elements, wherein said one or more transcription control elements comprises a promoter; and wherein said DNA is administered free from *ex vivo* cells;  
such that the cytokine encoded by said DNA is expressed *in vivo*, and  
such that said cytokine is present in the blood stream of said mammal in an amount effective to treat said cancer, or metastasis thereof.

Please substitute the following claim 3 for the pending claim 3:

*C2 Sub B2* 3. (Once amended) The method of claim 1, wherein said one or more transcription control elements comprises a polyadenylation signal and transcription termination signal.

Please substitute the following claim 4 for the pending claim 4:

*C* 4. (Once amended) The method of claim 1, wherein said cancer is selected from the group consisting of renal cell carcinoma, colorectal carcinoma, lymphoma, Kaposi's sarcoma, melanoma, prostate cancer, ovarian cancer, lung cancer, liver cancer, head and neck cancer, bladder cancer, uterine cancer, bone cancer, leukemia, breast cancer, non-melanoma skin cancer, glioma, solid cutaneous tumor, epidermoid carcinoma, metastases of any of thereof, and combinations of any of thereof.

Please substitute the following claim 7 for the pending claim 7:

*C3 Sub B3* 7. (Once amended) The method of claim 1, wherein said muscle tissue is selected from the group consisting of skeletal muscle, smooth muscle, or myocardium.

Please substitute the following claim 9 for the pending claim 9:

*C4* 9. (Once amended) The method of claim 1, wherein said cytokine is selected from the group consisting of IFN $\alpha$ , IFN $\beta$ , IFN $\gamma$ , IFN $\delta$ , IFN $\epsilon$ , IFN $\zeta$ , IFN $\eta$ , IFN $\theta$ , IFN $\iota$ , IFN $\kappa$ , IFN $\lambda$ , IL-1, IL-2, IL-4, IL-7, IL-12, IL-15, IL-18, GM-CSF, and a combination of any of thereof.

Please substitute the following claim 10 for the pending claim 10:

a4  
10. (Once amended) The method of claim 1, wherein said active fragment of a cytokine is selected from the group consisting of an active fragment of IFN $\omega$ , an active fragment of IFN $\alpha$ , an active fragment of IFN $\tau$ , an active fragment of IFN $\gamma$ , an active fragment of IFN $\beta$ , an active fragment of IL-1, an active fragment of IL-2, an active fragment of IL-4, an active fragment of IL-7, an active fragment of IL-12, an active fragment of IL-15, an active fragment of IL-18, an active fragment of GM-CSF, and a combination of any of thereof.

Please substitute the following claim 30 for the pending claim 30:

a5  
30. (Once amended) The method of claim 1, wherein said cancer is melanoma or metastasis thereof.

Please substitute the following claim 33 for the pending claim 33:

33. (Once amended) The method of claim 1, wherein said cancer is glioma.

a6  
[Please substitute the following claim 34 for the pending claim 34:]

34. (Once amended) The method of claim 1, wherein said cancer is epidermoid carcinoma.

[Please substitute the following claim 35 for the pending claim 35:]

Sub B4  
35. (Once amended) The method of claim 1, wherein said DNA is dissolved in an aqueous solution

Please substitute the following claim 38 for the pending claim 38:

am ~~Sub 38~~  
38. (Once amended) The method of claim 1, wherein said DNA is administered free from association with transfection-facilitating proteins, viral particles, liposomes, cationic lipids, and calcium phosphate precipitating agents.

[Please substitute the following claim 39 for the pending claim 39:]

39. (Once amended) The method of claim 1, wherein said DNA is administered as a complex of said DNA and one or more cationic compounds selected from the group consisting of cationic lipids, cationic peptides, cationic proteins, cationic polymers other than lipids or peptides, and mixtures thereof.

Please substitute the following claim 42 for the pending claim 42:

as ~~Sub 42~~  
42. (Once amended) The method of claim 1, wherein said DNA encodes at least one additional cytokine, or active fragment thereof, through operable association with a promoter, wherein said additional cytokine is expressed *in vivo*.

[Please substitute the following claim 43 for the pending claim 43:]

~~Sub 43~~  
43. (Once amended) The method of claim 1, wherein said DNA comprises a region regulating gene expression.

Please substitute the following claim 46 for the pending claim 46:

ag  
46. (Once amended) A method of treating cancer, or metastasis thereof, in a mammal, comprising:

the method of claim 1 in combination with one or more additional cancer treatment methods selected from the group consisting of surgery, radiation therapy, chemotherapy, immunotherapy, and gene therapy.

Please substitute the following claim 50 for the pending claim 50:

50. (Once amended) The method of claim 1, wherein said mammal is human.

Please substitute the following claim 66 for the pending claim 66:

66. (Once amended) A method of treating cancer in a mammal, comprising:  
administering into a body cavity of said mammal a non-infectious, non-integrating DNA encoding a cytokine, or an active fragment thereof, through operable association with a promoter, and wherein said DNA is administered free from *ex vivo* cells or *ex vivo* cellular material; such that said cytokine is delivered to a tumor in a therapeutically effective amount.

Please substitute the following claim 78 for the pending claim 78:

78. (Once amended) A method of selectively transfecting malignant cells in a body cavity of a mammal comprising:  
administering into a body cavity of said mammal a non-infectious, non-integrating DNA encoding a molecule, or an active fragment thereof, through operable association with a promoter, and wherein said DNA is administered free from *ex vivo* cells or *ex vivo* cellular material; such that said molecule is delivered substantially to and expressed in malignant cells within said body cavity.